

CLAIMS

1. A substantially pure polypeptide, which comprises at least one amino acid sequence selected from the group consisting of:
 - 5 (a) an amino acid sequence selected from Rv2653c, Rv2654c or RD1-ORF5;
 - (b) an immunogenic portion of any one of the sequences in (a); and
 - (c) an amino acid sequence analogue having at least 70% sequence identity to any one of the sequences in (a) or (b) and at the same time being immunogenic.
- 10 2. A substantially pure polypeptide according to claim 1, wherein the amino acid sequence analogue has at least 80% sequence identity to any of the sequences in (a) or (b).
3. A fusion polypeptide, which comprises at least one amino acid sequence according to claim 1 and at least one fusion partner.
- 15 4. A fusion polypeptide according to claim 3, wherein the fusion partner comprises a polypeptide fragment selected from the group consisting of:
 - (a) a polypeptide fragment derived from a virulent mycobacterium;
 - (b) a polypeptide according to claim 1; and
 - 20 (c) at least one immunogenic portion of any of such polypeptides in (a) or (b).
5. A polypeptide, which comprises at least one amino acid sequence according to claim 1 which is lipidated so as to allow a self-adjuvating effect of the polypeptide.
- 25 6. An immunogenic composition comprising at least one polypeptide according to claim 1.
7. An immunogenic composition according to claim 6, which is in the form of a vaccine.
8. An immunogenic composition according to claim 6, which is in the form of a skin test reagent.
- 30 9. A nucleic acid fragment in isolated form which
 - (a) comprises at least one nucleic acid sequence which encodes a polypeptide as defined in claim 1, or comprises a nucleic acid sequence complementary thereto;
 - 35 and/or

- (b) has a length of at least 10 nucleotides and hybridizes under stringent hybridization conditions with a nucleotide sequence selected from Rv2653c, Rv2654c or RD1-ORF5, or a nucleotide sequence complementary to any one of these sequences; or with a nucleotide sequence selected from a sequence in (a).

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10. A nucleic acid fragment according to claim 9, which is a DNA fragment.

11. A replicable expression vector, which comprises at least one nucleic acid fragment according to claim 9.

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12. A transformed cell harbouring at least one vector according to claim 11.

13. A method for producing a polypeptide according to claim 1, comprising:

- (a) inserting a nucleic acid fragment according to claim 12 into a vector which is able
15 to replicate in a host cell, introducing the resulting recombinant vector into the host cell, culturing the host cell in a culture medium under conditions sufficient to effect expression of the polypeptide, and recovering the polypeptide from the host cell or culture medium;
- (b) isolating the polypeptide from a whole mycobacterium from culture filtrate or from
20 lysates or fractions thereof; or
- (c) synthesizing the polypeptide.

14. A method of diagnosing tuberculosis caused by virulent mycobacteria in an animal, including a human being, comprising intradermally injecting, in the animal, at least one
25 polypeptide according to claim 1 or an immunogenic composition according to claim 6, a positive skin response at the location of injection being indicative of the animal having tuberculosis, and a negative skin response at the location of injection being indicative of the animal not having tuberculosis.

30 15. A method for immunising an animal, including a human being, against tuberculosis caused by virulent mycobacteria comprising administering to the animal at least one polypeptide according to claim 1 or an immunogenic composition according to claim 6.

35 16. A monoclonal or polyclonal antibody, which is specifically reacting with a polypeptide according to claim 1 in an immuno assay, or a specific binding fragment of said antibody.

17. A pharmaceutical composition which comprises an immunologically responsive amount of at least one member selected from the group consisting of:

- 5 (a) a polypeptide selected from Rv2653c, Rv2654c or RD1-ORF5, or an immunogenic portion thereof;
- (b) an amino acid sequence which has a sequence identity of at least 70% to any one of said polypeptides in (a) and is immunogenic;
- (c) a fusion polypeptide comprising at least one polypeptide or amino acid sequence according to (a) or (b) and at least one fusion partner;
- 10 (d) a nucleic acid sequence which encodes a polypeptide or amino acid sequence according to (a), (b) or (c);
- (e) a nucleic acid sequence which is complementary to a sequence according to (d);
- (f) a nucleic acid sequence which has a length of at least 10 nucleotides and which hybridizes under stringent conditions with a nucleic acid sequence according to
- 15 (d) or (e); and
- (g) a non-pathogenic micro-organism which has incorporated therein a nucleic acid sequence according to (d), (e) or (f) in a manner to permit expression of a polypeptide encoded thereby.

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